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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/590,284

06/09/00

GOLDENBERG

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018733-0967

HM12/0612

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EXAMINER

ROARK, J

ART UNIT

PAPER NUMBER

1644

7

DATE MAILED:

06/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/590,284

Applicant(s)

GOLDENBERG ET AL.

Examiner

Jessica H. Roark

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Restriction Requirement

1. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Prior to setting forth the restriction requirement the following is noted:
The claims are directed to a number of methods which employ anti-B cell antibodies either alone or in combination with other regimens targeting T cells, plasma cells, macrophages or inflammatory cytokines. These methods employ products that are recognized in the art to be distinct, since they affect different cellular populations (T cells, versus plasma cells versus macrophages) or different cellular mediators (inflammatory cytokines) and therefore are utilized in different patient populations. However, these multimodal treatments appear to be directed to therapeutic compositions that are art-recognized for the treatment of the particular diseases recited in claim 7.

Therefore, the compositions further comprising the secondary therapeutics:

A) will be considered to be *limited to secondary therapeutics appropriate for an elected disease*, as required below; and

B) will be considered obvious over any prior art anticipating or rendering obvious a method of treating the disease elected below comprising administering the first therapeutic of at least one antibody to a B cell antigen.

If Applicant does not agree with this assessment with respect to the second therapeutic composition, *an additional restriction requirement will be made* placing methods employing at least one anti-B cell antibody and *each type of secondary composition* (e.g., those directed against T cells, plasma cells, macrophages and inflammatory cytokines) in separate restriction GROUPS since separate fields of search would be required to address methods employing these compositions.

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Species Election

3. Claim 7 is generic to a plurality of disclosed patentably distinct species comprising different autoimmune diseases. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

In addition, since the specificity of the "secondary therapeutic" of e.g., claims 8, 16, and 17; as well as the "second arm" of the bispecific antibody of claim 30, is dependent upon the disease treated by the method; Applicant is **further required** to elect a consonant specificity for the secondary therapeutic, e.g. a secondary therapeutic against the inflammatory cytokine TNF α if the elected autoimmune disease is rheumatoid arthritis.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Claims 12 and 21 are generic to a plurality of disclosed patentably distinct species comprising different anti-B cell antibodies, either unconjugated or conjugated. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

In addition, Applicant is required to identify an ultimate species if anti-CD22 is elected as the anti-B cell specificity. For example, an indication of the combination of CD22 epitopes elected as the ultimate species from claim 6 must be provided; as well as whether or not any anti-CD22 antibody used in the method is conjugated to any of the labels of claim 21.

Further, since the specificity of the conjugated form of the antibody in claim 21 is dependent upon the disease treated by the method; Applicant is **further required** to elect a specificity for the conjugate that is consonant with the disease election made supra.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark whose telephone number is (703) 605-1209. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
June 5, 2001

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PRIMARY EXAMINER
TECH CENTER 1600
6/6/01